DEPARTMENT OF THE ARMY
HEADQUARTERS, WALTER REED ARMY MEDICAL CENTER
6900 Georgia Avenue, N.W.
WASHINGTON, DC 20307-5001

WRAMC Regulation
No. 40-22

1 May 2002

Medical Services
DECENTRALIZED LABORATORY TESTING

1. History
This publication is a revision of this regulation. The changes have not been highlighted.

2. Applicability
The provisions of this policy are applicable to all elements of WRAMC that perform clinical laboratory testing but are not an organizational element of the Department of Pathology and Area Laboratory Services (DPALS). This does include inpatient and outpatient testing performed by a health-care provider as part of a professional examination. It does not apply to the following:

a. Any laboratory performing testing for forensic purposes only.

b. Research laboratories that test human specimens but do not report patient specific results.

c. Laboratories regulated by DoD Instruction 1010.1, forensic toxicology and drug testing laboratories.

3. Purpose
To establish policies, responsibilities and procedures for decentralized laboratory testing at Walter Reed Army Medical Center (WRAMC).

4. References

a. MEDCOM Supplement 1 to Army Regulation 40-22, Army Medical Treatment Facilities General Administration.

b. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) Accreditation Manual for Pathology and Clinical Laboratory Services.

c. College of American Pathologists (CAP) Laboratory Accreditation Program.

d. Public Law 100-578, Clinical Laboratory Improvement Amendments (CLIA) of 1988 and Code of Federal Regulations (CFR) 42.

e. AFIP Pamphlet 40-24, Department of Defense Clinical Laboratory Improvement Program (DoD CLIP).

f. Memorandum, SGPS-PSQ, Subject: Clinical Laboratory Improvement Program (CLIP).

*This regulation supersedes WRAMC Reg 40-22, dated 2 August 1999.

5. Definitions

a. CLIA 88: Public Law 100-578, The Clinical Laboratory Improvement Amendments of 1988.

b. CLIP: The Department of Defense Clinical Laboratory Improvement Program. Established to comply with the provisions of CLIA 88 as a result of a memorandum of agreement between the Department of Defense (DoD) and the Department of Health and Human Services (DHHS). The Center for Clinical Laboratory Medicine (CCLM) is the office established by DoD at the Armed Forces Institute of Pathology (AFIP) to administer the CLIP.

c. JCAHO: Joint Commission on Accreditation of Healthcare Organizations.

d. CAP: College of American Pathologists.

e. Laboratory: A facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of or the assessment of the health of human beings. These examinations also include procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

f. Special Function Laboratories: A JCAHO term for hospital laboratories not under the supervision of the main laboratory director where *in vitro* laboratory procedures are performed, the results of which become a part of the medical record. The services are performed within a designated unit, the results are used for patient diagnosis and care and the laboratory employs one or more full or part-time personnel who primarily perform analytical procedures.

g. Laboratory Director: The individual who provides overall management and direction for the laboratory. The director is responsible for ensuring that testing personnel are competent to perform test procedures, test results are reported accurately, promptly, proficiently, and assuring compliance with all applicable regulations.

h. Analyte: A substance or constituent for which the laboratory conducts testing.

i. Categories of tests by complexity: Laboratory tests are categorized as waived tests, tests of moderate complexity, or tests of high complexity. The categorization of commercially marketed *in vitro* diagnostics tests under CLIA is now the responsibility of the Food and Drug Administration (FDA). A **CLIA database** is now available. This database contains the commercially marketed in vitro systems categorized by the FDA since January 31, 2000 and tests categorized by the Centers for Disease Control and Prevention (CDC) prior to that date. Each level of complexity has differing requirements for the training and experience of supervisory and testing personnel. A test system that is not classified by complexity is considered to be highly complex. An additional category term, Provider Performed Microscopy (PPM), is explained in j. below.

j. Provider Performed Microscopy: Microscopic examination performed by physicians, dentists and mid-level practitioners (nurse practitioner, nurse midwife, physician assistant) as a part of their professional examination. Such testing is performed with the use of a microscope and during the patient's visit.

k. Waived Testing: On February 28, 1992, regulations were published to implement CLIA. In the regulations, waived tests were defined as simple laboratory examinations and procedures that are cleared by the FDA for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or pose minimal risk of harm to the patient if the test is performed incorrectly.

l. Minimally Complex Tests: A term used in CLIP that is synonymous with Waived Testing.

6. Responsibilities

a. Laboratory Certification. All laboratories must apply for and be granted the appropriate certificate from the CCLM. All requests will be routed through the Chief, DPALS who will provide the Hospital Commander with a recommendation regarding the requested certificate. All certification requests must be signed by the Commander. The signed request represents the Commander's authorization for the laboratory to operate. Contract laboratories within the hospital must be registered in accordance with CLIA 88.

b. Chief, DPALS will:

(1) Provide guidance and assistance for the certification process including a recommendation to the Commander.

(2) Provide advice and guidance on any question or problem relating to the personnel standards and the establishment and maintenance of quality control systems.

(3) Provide recommendations for log sheets used to document instrument maintenance and function checks on equipment used for testing.

(4) Provide advice regarding the interpretation of statistical analysis of quality control data.

(5) Provide training to supervisory personnel working in decentralized laboratories concerning interpretation, documentation and corrective actions required for implementation of an acceptable quality control program.

(6) Send CLIP registration applications to the CCLM. On receipt of certificates by the DPALS Performance Improvement office, a copy will be forwarded to the named laboratory director.

c. Each decentralized laboratory will:

(1) Establish a comprehensive quality control program and a written standard operating procedure for each procedure performed. The laboratory director will review standard operating procedures at least annually.

(2) Use quality control materials appropriate to each procedure performed. Document satisfactory reactivity, sensitivity and specificity of test reagents and materials at the frequency specified for that procedure.

(3) Document inspection, maintenance and performance data for each piece of equipment used in performing test procedures.

(4) Document the training and experience of the individuals performing laboratory tests and provide in-service education opportunities consistent with the size and the needs of the laboratory.

(5) Participate in an external quality assurance program (proficiency testing) appropriate to the size and the needs of the laboratory.

Participation will entail testing "unknown" specimens provided through the CAP or other recognized external proficiency testing survey. DPALS participates in the CAP proficiency testing program and will assist labs in determining their needs.

(6) Maintain results of patient testing, quality control records and proficiency testing results for two years.

d. The Laboratory Director of each decentralized lab will oversee the operation of their lab in accordance with the appropriate standards. This includes, but is not limited to:

(1) The regular review of quality control data.

(2) The regular review of proficiency testing data.

(3) Taking appropriate action when tolerance limits are exceeded.

(4) The annual review of Standard Operating Procedures.

(5) Ensuring competency assessment of each individual performing testing prior to assumption of duties, six months later and annually thereafter for personnel actively involved in testing. Competency assessment must be performed more frequently for those individuals that perform testing on an irregular or infrequent basis.

7. Policies

A goal of this command is to insure that the patients of this medical treatment facility receive high quality clinical laboratory testing whenever, wherever, and by whoever performed. It is also a goal to comply with CCLM and JCAHO standards as they apply to laboratory testing. To achieve this, a four-fold approach will be used.

a. Authorization.

(1) Any element of WRAMC desiring to operate a decentralized lab must receive specific authorization. Evidence of this authorization is certification by the CCLM. Contract laboratories must comply with registration requirements of CLIA 88.

(2) Providers (physicians, dentists and mid-level practitioners) are specifically authorized to perform testing as long as they comply with the provisions of this regulation and have the appropriate certificate from the CCLM.

b. Standards. All clinical laboratory testing will be performed in accordance with CLIP and JCAHO standards.

c. Accreditation. All decentralized laboratories performing moderately and highly complex testing will seek and gain CAP accreditation

d. Workload Recording. By the 15th of each month, all decentralized laboratories performing moderately and highly complex testing will provide DPALS Laboratory Information Systems office a report of the previous month's total number of patient and quality control tests performed.

8. Provider-Performed Microscopy Procedures

Providers, as described above, may perform certain tests as a part of their professional examination. Specimen logs and specific quality control logs are not required. The results are entered directly into the patient's chart. Each lab must have the appropriate registration certificate.

a. The following tests are considered to be Provider-Performed Microscopy Procedures:

(1) Wet mounts.

(2) KOH preps.

(3) Cervical mucous ferning.

(4) Pinworm examinations.

(5) Urine sediment examinations.

(6) Post-coital direct examinations of cervical or vaginal mucous.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

(9) Synovial fluid examination.

b. Policy. Decentralized laboratories that perform one or more of the tests listed in paragraph 7 must comply with the following standards:

(1) Each lab must have the appropriate registration certificate. These tests must be performed under a certificate for PPM procedures or a certificate for moderate or high complexity.

(2) Each test performed must have an SOP, including specimen collection.

(3) The microscope(s) used to perform this testing must be cleaned, serviced regularly, and in good working order.

(4) The results are entered directly into the patient's chart and include the date and time of testing and the name of the individual who performed the test.

(5) Twice a year the accuracy and reliability of test results obtained is verified. This is accomplished by duplicate reading of a defined number of slides.

9. Minimally Complex Tests

Laboratories performing only minimally complex testing have requirements that vary somewhat from the above.

a. As defined by CCLM, the following are considered to be minimally complex tests:

(1) Dipstick or tablet urinalysis (non-automated) for the following analyses: Bilirubin, Glucose, Hemoglobin, Ketone, Leucocyte esterase, Nitrite, pH, Specific gravity, Urobilinogen, and Protein.

(2) Fecal occult blood.

(3) Urine pregnancy test - visual color comparison tests.

(4) Hemoglobin - copper sulfate - nonautomated or single analyte instrument.

(5) Blood glucose by monitoring devices cleared specifically by the FDA for home use.

(6) CLOtest – detects the urease enzyme of Helicobacter pylori

(7) Cholestech LDX

b. Policy. Decentralized laboratories that perform one or more of the tests listed in paragraph 8a must comply with the following standards:

(1) Except for blood glucose, which is a definitive waived test, waived testing results are used for screening purposes only. Any abnormal result must be confirmed by forwarding a sample to the main laboratory.

(2) A laboratory director and those authorized to perform testing are designated in writing.

(3) Individuals performing tests must have adequate and specific training and documented orientation. Individual competency assessment must be documented at specified intervals.

(4) Each test performed must have an SOP that addresses each of the following elements when applicable: Specimen Collection, Specimen Preservation, Instrument Calibration, Quality Control and Remedial Action, Equipment Performance and Evaluation, and Test Performance.

(5) Quality control checks are conducted on each procedure as specified in the SOP. At a minimum, manufacturers' instructions are followed, appropriate quality control and test records are maintained for at least two years, and administrative paperwork is submitted as necessary to maintain accreditation and registration.

10. Laboratory Oversight
Chief, DPALS has oversight responsibility for all clinical laboratory testing:

a. Chief, DPALS will:

(1) Inspect each decentralized laboratory and provide a report with recommendations to the laboratory at least once quarterly. For moderate and high complexity decentralized laboratories, the Medical Director shall be informed of any deficiencies via electronic mail.

(2) Provide each decentralized laboratory an inspection checklist appropriate for the volume and type of testing performed.

(3) Appoint inspectors appropriate for the type of testing performed. Inspectors may be pathologists, laboratory officers, military medical laboratory technicians (91K, E-6 or higher), or civilian medical technologists.

(4) Maintain records of inspection, recommendations and reports of corrective action.

b. Each decentralized laboratory will:

(1) Maintain an inspection binder or notebook containing the following:

(a) CLIP certificate.

(b) Current WRAMC regulation pertaining to decentralized laboratory testing.

(c) Standard Operating Procedure (SOP) for each test performed.

(d) Name of Lab Director and list of authorized testing personnel.

(e) In-service training program; training records will be kept in individual competency file folders

(f) Most recent inspection report from DPALS.

(g) Quality Control records for two years; (Exception: instruments with connectivity will have QC records maintained on the central workstation).

(h) Results of CAP proficiency test results for two year. This requirement applies only to sites performing moderate and high complexity testing.

(2) Within 30 working days of receipt of inspection reports, provide documentation to Chief, DPALS, of action taken to correct any deficiencies.

(3) Report to DPALS any change in personnel or testing methodology that may require an amendment of their certificate as soon as the change occurs. Submit this information in the form of a request to amend the held certificate.

The proponent agency of this publication is the Department of Pathology and Area Laboratory Services. Users are invited to send suggestions and comments on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, Walter Reed Army Medical Center, ATTN: MCHL-U, 6900 Georgia Avenue NW, Washington, DC 20307-5001.

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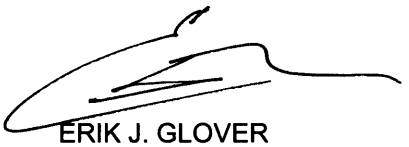

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